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Attorney Docket No.: 2307O-689-1 Client Reference No.: 96-185-2

> #23 5/0/99 T.Gra

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Examiner:

Ungar, S.

Gray et al.

Art Unit:

1642

Patent No.:

RESPONSE TO RESTRICTION

Application No.: 08/731,499

Filed: October 16, 1996

For: GENES FROM THE 20Q13 AMPLICON AND THEIR USES

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

The following is offered in response to the Office Action mailed February 21, 1999. Applicants elect with traverse to prosecute the claims of Group 9. This election is the same as the election of species previously made in the response filed March 27, 1998. Since that election, applicants have received and responded to a substantive Office Action. Surprisingly, the PTO now asserts that despite substantive prosecution, a further restriction is required in this application.

According to the MPEP, where claims can be examined together without undue burden, the Examiner *must* examine the claims on the merits even though they are directed to independent and distinct inventions. *See*, the MPEP at 803.01. In establishing that an "undue burden" would exist for co-examination of claims, the Examiner *must* show that examination of the claims would involve substantially different prior art searches, making the co-

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examination burdensome. To show undue burden resulting from searching difficulties, the Examiner *must* show that the restricted groups have a separate classification, acquired a separate status in the art, or that searching would require different fields of search (MPEP at § 808.02).

In the present restriction, all the groups are indicated as classified under Class 536, subclass 23.1. Each group corresponds to what had previously indicated as a species. The Examiner has provided little or no reasoning to show that the groups meet the other two criteria required under §808.02. Instead, the Examiner simply states that the claimed nucleic acids are "biologically and chemically distinct". Without more to support this assertion, the restriction is improper and should be withdrawn.

In addition, applicants note that claims 1, 22, 23, and 45 have been placed in each of the Groups identified in the Action. The courts have long held that an Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions. See, In Re Weber, Soder and Boksay 198 USPQ 328, 331 (C.C.P.A. 1978). See also, In Re Haas 179 USPQ 623, 624, 625 (In Re Haas I) (C.C.P.A. 1973) and In Re Haas 198 USPQ 334-337 (In Re Haas II) (C.C.P.A. 1978).

The courts have definitively ruled that the section of the patent statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. See, In Re Weber, Soder and Boksay, In Re Haas I and In Re Haas II. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in In Re Weber, Soder and Boksay:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334.

Moreover, MPEP §803.04, citing this case law, makes clear that when, as here, a claim includes a Markush group that contains a number of unrelated inventions, a *species* election is proper. In conclusion, Applicants respectfully submit that in light of the conclusory

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statements used to support the restriction, the Examiner has not provided sufficient reasoning to establish undue burden of examining all the Groups in a single application. Moreover, there is no statutory authority for imposing a restriction requirement on a single claim, as was done here. The courts have expressly held that the type of restriction requirement made by the Examiner is improper. Withdrawal of the restriction is respectfully requested.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (415) 576-0200.

Respectfully submitted,

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